

Device Description

The Hitachi EUB-5500 Diagnostic Ultrasound Scanner is a Track 3 Diagnostic Ultrasound Pulsed Doppler and Pulsed Echo Imaging System capable of the following operating functions:

B Mode

M Mode

Pulsed Doppler

Continuous Wave Doppler

Color Flow

Amplitude Doppler

NOV 2 2 2006

Harmonic imaging

Superficial musculoskeletal imaging

3D imaging

4D imaging

Safety

As a Track 3 ultrasound device, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner complies with the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (1992) – published by NEMA as UD-3.

With respect to limits on acoustic outputs, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner complies with the guideline limits set in the 510(k) Diagnostic Ultrasound Guidance – Revision: April 14, 1994.

With regard to general safety, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner is designed to comply with *IEC 606601-1 (1998) Medical Electrical Equipment, Part 1 – General Requirements for Safety.*



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUN 2 1 2007

Mr. Douglas J. Thistlethwaite Manager of Regulatory Affairs Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park TWINSBURG OH 44087

Re: K061608

Trade Name: EUB-5500 Diagnostic Ultrasound Scanner

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYO, IYN, and ITX

Dated: December 1, 2006 Received: December 4, 2006

Dear Mr. Thistlethwaite:

This letter corrects our substantially equivalent letter of November 22, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the EUB-5500 Diagnostic Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

EUP-B314 EUP-B512 EUP-C314G EUP-C516 EUP-C524 EUP-CC531 EUP-CV524 EUP-F334 EUP-L34T EUP-L52 EUP-L53 EUP-L53L EUP-L65 EUP-R53W EUP-R54AW-19,-33 EUP-S50A EUP-S52 Fujinon SP711

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact John Chen at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System:

EUB-5500

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	Р	P	P	P	P	P	p	
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa	
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb	
	Intra-operative (Neuro.)	P	P	P		P	P	P	
	Laparoscopic	P	P	P		P	P	P	
	Pediatric	P	P	P	P	P	P	P	
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd	
	Neonatal Cephalic	P	P	P		P	P	P	
Fetal Imaging	Adult Cephalic	P	P	P	P	Р_	P	P	
& Other	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph	
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf	
1	Trans-urethral								
	Trans esoph. (non Card.)								
	Musculo skel. (Convent.)	P	P	P		P	P	P	
	Musculo-skel. (Superfic.)	P	P	P		P	P	P	
	Intra-luminal	E							
	Other (spec.)								
	Cardiac Adult	P	P	P	P	P	P	P	
Cardiac	Cardiac Pediatric	P	P	P	P	P	P	P	
	Trans-esophageal (card.)	P	P	P		Р	P	P	
	Other (spec.)								
	Peripheral vessel	P	P	P	P	P	P	P	
Vessel	Other (spec.)							***************************************	

P = Previously Cleared, K032503; E = Added under Appendix E

Additional	Comments
Additional	Lomments

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of transrectal biopsy.
Subscript "f":	Includes imaging for guidance of transvaginal biopsy.
Subscript "g":	Includes imaging for guidance of trans-perineal biopsy.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
(PLEAS	SE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

<u>LEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)</u>

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: K0 (1608

Prescription Use (Per 21 CFR 801.109)

133

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System: Transducer: EUB-5500 EUP-B314

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
			3.7	LDWD				AL 44		
General (Track I only)	(Tracks I & III)	В	M	PWD	CWD	Color	Combined*	Other**		
Ophthalmic			<u> </u>	ļ		Doppler	(Spec.)	(Spec.)		
Ophthanine			12	12			 			
	Fetal	E	E	E		E	E	E		
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea		
	Intra-operative (Spec.)			<u> </u>						
	Intra-operative (Neuro.)									
	Laparoscopic			Ĺ			L			
	Pediatric									
	Small Organ (Spec.)									
	Neonatal Cephalic									
	Adult Cephalic									
& Other	Trans-rectal			1						
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult				7					
Cardiac	Cardiac Pediatric				1					
	Trans-esophageal (card.)									
	Other (spec.)									
	Peripheral vessel									
Vessel	Other (spec.)									

Additional	Comments
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT. and Radiological Devices

510(k) Number: ___

Prescription Use	
(Per 21 CFR 801.109)	

E = Added under Appendix E
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler, Harmonic Imaging.

System: Transducer:

EUB-5500 EUP-B512

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only) Ophthalmic	Specific (Tracks I & III) Ophthalmic	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthamile	Fetal	E	E	E					
	Abdominal	Ea	Ea	Ea		E	E	E	
	Intra operative (Spec.)	La	La	Ea		Ea	Ea	Ea	
	Intra operative (Spec.)								
					\rightarrow				
	Laparoscopic Pediatric								
	Small Organ (Spec.)						Ĺ		
Patul Imagaina	Neonatal Cephalic						ļ		
Fetal Imaging									
& Other	Trans-rectal								
	Trans-vaginal			 					
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo skel. (Convent.)								
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.)								
~ ··	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
	Peripheral vessel								
Vessel	Other (spec.)				***				

E = Added under Appendix E

Additional	Comments
Additional	Comments

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

D	
Prescription Use	
(Per 21 CFR 801	.109)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-5500 EUP-C314G Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic										
	Fetal	E	E	E		E	E	E		
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea		
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)				I					
	Laparoscopic									
	Pediatric	E	E	E		E	E	Е		
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	_ Ed	Ed		
_	Neonatal Cephalic									
	Adult Cephalic									
& Other	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
	Peripheral vessel									
Vessel	Other (spec.)									

E = Added under Appendix E

Additional	l Com	mante:
Additiona.	LOUII	ments.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT. and Radiological Devices

510(k) Number:_

Prescription Use. (Per 21 CFR 801.109)

^{*}Combination of each operating mode, B. M. PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-5500 EUP-C516 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic									
	Fetal	E	E	E		E	E	E	
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea	
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric Pediatric	E	E	E		E	Е	E	
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed	
	Neonatal Cephalic								
	Adult Cephalic								
& Other	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.)								
_	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.)								

E = Added under Appendix E

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
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	Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

Prescription Use _____(Per 21 CFR 801.109)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler. Harmonic Imaging.

System:

Transducer:

EUB-5500 EUP-C524

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only) Ophthalmic	Specific (Tracks I & III) Ophthalmic	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalinic	Fetal	E		-				
	Abdominal	E	E	E		E E	E	E
		E	<u> </u>	E		Е	E	E
	Intra-operative (Spec.)							
	Intra operative (Neuro.)		<u> </u>					
	Laparoscopic					· · · · · · · · · · · · · · · · · · ·		
	Pediatric (2)	E	Е	E		E	Е	E
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec
5	Neonatal Cephalic							
	Adult Cephalic							
& Other	Trans-rectal							
	Trans-vaginal						<u> </u>	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
1	Intra luminal							
	Other (spec.)							
	Cardiac Adult				Î			
Cardiac	Cardiac Pediatric						1	
	Trans-esophageal (card.)							
	Other (spec.)				1			
	Peripheral vessel							
Vessel	Other (spec.)							

E = Added under Appendix E

Additional	Comments
Additional	Communicates

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

Prescription Use	
(Per 21 CFR 801.109)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-5500 EUP-CC531 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application Mode of Operation										
		-								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic		-		-		2 орргог	(Spec.)	(Dpcc.)		
	Fetal	E	Е	E		Ð	E	Е		
	Abdominal									
	Intra-operative (Spec.)									
	Intra operative (Neuro.)									
	Laparoscopic									
	Pediatric									
	Small Organ (Spec.)							-		
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic						1			
& Other	Trans-rectal	Ee	Ee	Ee		Ee	Ee	Ee		
	Trans-vaginal	Éf	Ef	Ef		Ef	Ef	Ef		
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel				1					
Vessel	Other (spec.)									

Additional	Comments

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

Prescription Use	
(Per 21 CFR 801)	

E = Added under Appendix E
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler, Harmonic Imaging.

System:

EUB-5500 EUP-CV524

Transducer: EUP-C

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	ing or fluid flow analysis if the human body as follows: Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal	N	N	N.		N	N	N		
	Abdominal	N	N	N		N _	N	N		
	Intra-operative (Spec.)									
	Intra operative (Neuro.)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N		
	Small Organ (Spec.)	Nc	Nç	Nc	\Box	Ne	Nc	Nc		
	Neonatal Cephalic									
	Adult Cephalic									
& Other	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.)									

N = new indication.

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: K061608

Prescription Use _	
(Per 21 CFR 801.1	

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-5500

EUP-F334 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal Abdominal Intra operative (Spec.) Intra operative (Neuro.)	Eb	Eb	Eb		Eb	Eb	Eb	
	Laparoscopic Pediatric Small Organ (Spec.)	E Ec	E Ec	E Ec		E Ec	E Ec	E Ec E	
Fetal Imaging & Other	Neonatal Cephalic Adult Cephalic Trans-rectal	E	E	E		E	E	E	
	Trans-vaginal Trans-urethral Trans-esoph. (non-Card.)	Е	E	E		Е	Е	E	
	Musculo-skel. (Convent.) Musculo-skel. (Superfic.)								
	Intra-luminal Other (spec.)								
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.)								
n · 1	Other (spec.)		-						
Peripheral Vessel	Peripheral vessel Other (spec.)	E	Ē	E		E	E	Е	

E = Added under Appendix E

Additional Comments:

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Subscript "g":	Includes imaging for guidance of trans-perineal biopsy.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:

Prescription Use (Per 21 CFR 801.109)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler, Harmonic Imaging.

System:

EUB-5500 EUP-L34T Transducer:

Clinical Application			ing or fluid flow analysis if the human body as follows: Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	Ea Ed Ed	E E E E	E E E E		Ea E E E	E E E E E	E E E E		
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)	E	E	E		E	E	E		

E = Added under Appendix E

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: ___

Prescription Use	1/
	<u>-</u>
(Per 21 CFR 801.109)	

143

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler, Harmonic Imaging.

System:

Transducer:

EUB-5500 EUP-L52

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human hody as follows:

	ical Application	Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic	Ea E Ed	Ea E Ed	Ea E Ed		Ea E Ed	Ea E Ed	Ea E Ed	
Fetal Imaging & Other	Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.)								
	Musculo skel. (Convent.) Musculo skel. (Superfic.) Intra luminal Other (spec.)	E	Е	E		E	E	Ē	
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.)								
Peripheral Vessel	Peripheral vessel Other (spec.)	E	E	Е		Е	Е	Е	

E = Added under Appendix E

Additional	Commonto

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number:__

Prescription Use_ (Per 21 CFR 801.109)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-5500

Transducer:

EUP-L53

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clin	Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	₿	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea			
	Intra-operative (Spec.)										
	Intra operative (Neuro.)										
	Laparoscopic										
	Pediatric	E	E	E		E	E	E			
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed			
	Neonatal Cephalic										
	Adult Cephalic										
& Other	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	E	E	E		E	E	E			
	Musculo-skel. (Superfic.)	E	E	E		E	E_	E			
	Intra-luminal										
	Other (spec.)										
	Cardiac Adult										
Cardiac	Cardiac Pediatric										
	Trans-esophageal (card.)										
	Other (spec.)			L							
Peripheral	Peripheral vessel	E	E	E		E	E	E			
Vessel	Other (spec.)										

E = Added under Appendix E

Additional	Comments:
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Subscript "g":	Includes imaging for guidance of trans-perineal biopsy.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: Kobl608

Prescription Use	
(Per 21 CFR 801.109)	

145

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-5500

Transducer:

EUP-L53L

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	E	E	E		E	E	E		
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric	E	E	E		E	E	E		
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec		
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic					***				
& Other	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)	E	E	E		E	E	E		
	Musculo-skel. (Superfic.)	E	E	E		E	E	E		
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
	Peripheral vessel	E	E	E		E	E	E		
Vessel	Other (spec.)									

E = Added under Appendix E

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Add	itiona	l Com	ments

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
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Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: KO6668

Prescription Use (Per 21 CFR 801.109)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-5500 EUP-L65 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.)	E Ec Ec	E E Ec	E E Ec		E Ec	E E Ec	E Ec Ec		
	Musculo skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult	E	E	E		E	E	E		
Cardiac	Cardiac Pediatric Trans-esophageal (card.) Other (spec.)									
	Peripheral vessel Other (spec.)	E	E	E		E	E	E		

E = Added under Appendix E

Additional Comments:

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Subscript "g":	Includes imaging for guidance of trans-perineal biopsy.
Subscript "h":	Includes imaging for guidance of transrectal biopsy.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: KO 6/608

Prescription Use (Per 21 CFR 801.109)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:
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EUB-5500

EUP-R53W Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		ing or	ang or fluid flow analysis if the human body as follows: Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	E	E	E		E	E	E		
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)									

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> (Division Sign-Off) Division of Reproductive, Abdominal, ENT. and Radiological Devices

510(k) Number: __

Prescription Use	
(Per 21 CFR 801.109)	

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.
**Amplitude Doppler, Harmonic Imaging.

System:

EUB-5500

Transducer:

EUP-R54AW-19, -33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	lical Application					e of Operati		
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal Abdominal Intra operative (Spec.) Intra operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans rectal Trans vaginal Trans urethral Trans esoph. (non-Card.) Musculo skel. (Convent.) Musculo skel. (Superfic.) Intra luminal Other (spec.)	E	E	E		E	E	E
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.)							
Peripheral Vessel	Peripheral vessel Other (spec.)							

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number: K06/608

Prescription Use	V
(Per 21 CFR 801	

140

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:

EUB-5500 EUP-S50A Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application		7			le of Operati		
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	E	E	E	E	E	E	E
	Abdominal	E	E	E	E	E	E	Ē
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E	E	E	E	E
	Small Organ (Spec.)		<u> </u>					
	Neonatal Cephalic_		L					
	Adult Cephalic	E	E	E	E	E	E	E
& Other	Trans-rectal		<u> </u>				L	
	Trans-vaginal			<u></u>			<u> </u>	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)						ļ	
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)						<u> </u>	
Cardiac	Cardiac Adult	Е	E	E	E	E	E	E
	Cardiac Pediatric	E	E	E	E	Е	Е	E
	Trans esophageal (card.)		Ļ				<u> </u>	
	Other (spec.)							
	Peripheral vessel	E	E	E	E	Е	E	Е
Vessel	Other (spec.)							

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(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

System:	
Transduc	

EUB-5500 EUP-S52 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific . (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined*	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	E	E	E Ec	EEEc	E Ec	E Ec	E Ec
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.)	E	E	E	Е	E	E	E
Peripheral Vessel	Peripheral vessel Other (spec.)							

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510(k) Number: K06/608

Prescription Use _	
(Per 21 CFR 801.1	09)

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging.

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Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application					de of Operation		
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic Ophthalmic							
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	E						
Cardiac	Cardiac Adult Cardiac Pediatric Trans esophageal (card.) Other (spec.)							
Peripheral Vessel	Peripheral vessel Other (spec.)							

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Addi	tiona	l Cam	ments

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> (Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use _ (Per 21 CFR 801.109)

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^{**}Amplitude Doppler, Harmonic Imaging.